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TO:	PHONE:	FAX #:
U.S. Patent and Trademark Office Petitions Branch Attn: Karin Tyson	(703) 305 9284	(703) 308 6916

In re Interim Patent Term Extension of U.S. Patent No. 4,373,527
Patentee: Robert E. Fischell
Assignee: The Johns Hopkins University
Issue Date: February 15, 1983

From: Stephen B. Macbius
Sender's Direct Dial: 202 672 5569
Date: December 8, 2000
Client/Matter No: 047711/0100

MESSAGE:

Certificate of Transmission

I hereby certify that a Eighth Status Inquiry is being facsimile transmitted to the Patent and Trademark Office on December 8, 2000.

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Assistant to Stephen B. Macbius

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket No. 047711/0100

In re INTERIM PATENT TERM EXTENSION OF U.S. Patent No. 4,373,527

#H6

Patentee: Robert E. FISCHHELL

Assignee: The Johns Hopkins University

Issue Date: February 15, 1983

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PETITIONS OFFICE

EIGHTH STATUS INQUIRYAssistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Patentee filed a Status Inquiry on October 13 and 27, November 3, 10, 17, 24 and December 1, 2000, relating to the above-captioned interim extension application. A Request for Reconsideration of Notice of Final Determination of Ineligibility was filed in the U.S. Patent Office on May 8, 2000. The U.S. Patent Office indicated that it is trying to get a response from the FDA to a letter dated March 27, 2000 (copy enclosed), from Ms. Karyn Tyson of the U.S. Patent Office to Mr. David Read of the FDA, so that it can decide how to respond to the Request for Reconsideration. It has more than been 7 months since that letter was sent.

On October 13 and 27, November 3, 10, 17 and 24, and December 1 2000, the patentee filed a status inquiry with the U.S. Patent Office with a copy to Mr. Read at the FDA. On October 19, 2000, the undersigned received a phone call from Ms. Claudia Grillo of the FDA, who indicated that the FDA is in the process of preparing a response to the Patent Office's March 27th letter, and that a response should be complete within a couple of weeks. The patentee hereby requests a status report as to the preparation of the FDA's response.

The patentee is required to file a renewed application for interim extension during a period that starts 60 days before the first year interim extension expires (i.e., such renewed application would need to be filed around December 15, 2000), but in this case, patentee has not yet even been granted the first extension, and the first-year period is drawing to a close.

Respectfully submitted,

Dec. 8, 2000
Date

FOLEY & LARDNER
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Stephen B. Maebius
Stephen B. Maebius
Attorney for Applicant
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cc: Mr. David T. Read
Acting Director Regulatory Policy Staff, CDEV
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, Maryland 20852

MAR 27 2000

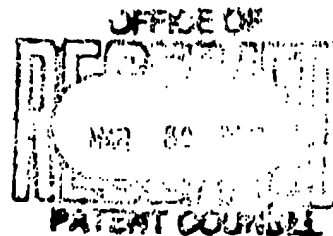


UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
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OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

David T. Read
Acting Director Regulatory Policy Staff, CDEV
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

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Dear Mr. Read:

PETITIONS OFFICE

The attached application for interim patent term extension of U.S. Patent No. 4,373,527 was filed on January 28, 2000, under 35 U.S.C. § 156(d)(5).

The assistance of your Office is requested in confirming that the product identified in the application, Minimed 2007, is subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g)(3)(B)(ii).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156(d)(5) only if an application under section 515 of the Federal Food, Drug and Cosmetic Act was initially submitted prior to January 28, 2000 for the product Minimed 2007.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Francis A. Cooch
Office of Patent Counsel
Johns Hopkins University
Applied Physics Laboratory
11100 Johns Hopkins Road/Laurel MD 20723-6099

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